

### **REMARKS**

Claims 124-130 and 143-149 are pending in the application. Claims 124, 125, 128, 130, 143 and 147 are amended by adding the term "irradiated" for clarity. No new matter has been added. The office action is discussed below.

#### ***Claim Interpretation, Effective Filing Date and Response to Arguments***

The examiner believes that claims 124-127, 130 and 143-149 encompass the "MIR" method disclosed in SN '744 and the irradiation and subsequent melting method ("IR-SM") first disclosed in SN 08/726,313. Thus, claims 124-127, 149 wherein the melting step precedes the irradiation step have an effective filing date of 02/13/2006. The examiner also believes that claims 147-149 wherein the irradiation step precedes the melting step have an effective filing date of 11/02/1996. Therefore, according to the examiner, the earliest effective filing date of the instant claims wherein the method steps comprise irradiation followed by melting the irradiated UHMWPE is considered to be the 10/02/1996 filing date of SN 08/726,313.

Applicants respectfully disagree with the examiner and submit that instant specification has support for a process for irradiating a fabricated article comprising ultrahigh molecular weight polyethylene and heating the irradiated fabricated article.

Applicants also submit that the examiner has analyzed the claims in view of the specification, "reading limitations of the specification into a claim" is "impermissible". Applicants refer that claims are to be given their broadest reasonable interpretation consistent with applicants' specification. See *In re Zletz*, 13 USPQ2d 1320, 1322 (Fed Cir. 1989) (holding that claims must be interpreted as broadly as their terms reasonably allow). Also see MPEP § 2111.01 (Rev. 5, August 2006 at 2100-38). However, the court explained that "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from 'reading limitations of the specification into a claim,' ..... i.e., the impermissible importation of subject matter from the specification into the claim.). See also *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997)...."

In this case, the examiner is trying to limit the claims in view of certain embodiments of the specification and not allowing the steps that are inherently disclosed in the specification. Applicants refer to the dictates of MPEP § 2163.07 and § 2164 (Rev. 5, August 2006 at 2100-185-186) that:

"By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973)."

The examiner also believes that the priority application SN '744 does not support the heating step after irradiation, thus, instant claims are anticipated by Shen, Hyon, Salovey or Shalaby. In response, applicants refer to the Rule 131 declaration filed in a related case. Applicants note that, this application is a continuation of U.S. Serial No. 09/572,324, which is a continuation of U.S. Serial No. 09/764,445, filed February 13, 1996. Apparently, the examiner could not locate the data presented in the declaration filed on July 16, 2004 in the related application serial No. 10/197,209, which are sufficient to support the invention of all the claimed process steps prior to the priority dates of the cited references.

Applicants herewith provide a copy of the Rule 1.131 declaration that was filed on July 16, 2004 in the related application (Serial No. 10/197,209) and show completion of the instantly claimed invention prior to January 20, 1995. Accordingly, the Shen, Hyon, Salovey or Shalaby patents are not prior art. Therefore, applicants submit that the rejection should be withdrawn. See *In re Spiller*, 500 F.2d 1170 (CCPA 1974); *In re Stempel*, 241 F.2d 755 (CCPA 1957).

***Claim Rejections - 35 U.S.C. § 112:***

On page 4 of the office action, the examiner rejected claims 124-130 and 143-149 and alleged as being indefinite. According to the examiner the method claims 124, 125, 130, 143 and 147 do not clearly set forth whether the fabricated article in the step of heating the fabricated article is the irradiated fabricated article containing free radicals formed in the irradiation step. The examiner also asserts that the method for producing cross-linked UHMWPE included in claims 128 and 129 does not clearly set forth whether the UHMWPE in the step of melting the UHMWPE is the irradiated UHMWPE containing free radicals formed in the irradiation step. Applicants traverse this rejection on the grounds that the examiner has not provided reasons why the skilled person would not understand the claims. Applicants clarify that the method claims 124, 125, 130, 143 and 147 are clearly set forth as a step by step process, which recites "irradiating a fabricated article" and the next step of "heating (or melting, in case of claim 147) the fabricated article." Similarly, claims 128 and 129 also clearly set forth the step of "irradiating the UHMWPE" and then the step of "melting the UHMWPE." However, in order to expedite the prosecution and for additional clarity, applicants amend claims 124, 125, 128, 130, 143 and 147 by adding the term "irradiated." Withdrawal of the rejection is therefore requested.

***Claim Rejections - 35 U.S.C. § 102:***

On pages 4-5 of the office action, the examiner rejected claims 124-130 and 143-149, and alleged as being anticipated by Shen *et al.* (6,228,900, which claims priority to a provisional application serial no. 60/017,852, filed July 9, 1996).

Applicants respectfully traverse the rejection and indicate that the instant application claims priority to U.S. Serial No. 08/726,313 (filed October 2, 1996), which was filed as a continuation-in-part of U. S. Serial No. 08/600,744 (filed February 13, 1996). Therefore, the Shen patent does not qualify as prior art under 35 USC § 102(e) because applicant's initial filing antedates Shen's filing dates. Withdrawal is therefore solicited.

On page 5 of the office action, the examiner rejected claims 126-129 and 143-149, and alleged as being anticipated by Hyon *et al.* (6,168,626, claiming a priority date of May 6, 1996). Applicants respectfully traverse the rejection and refer to the discussion above that applicant's initial filing antedates Hyon's filing dates. Hyon *et al.* is not a prior art to instant application, thus the rejection is improper. Withdrawal is therefore solicited.

On pages 5-6 of the office action, the examiner rejected claims 126-129 and 143-149, and alleged as being anticipated by Salovey *et al.* (6,281,264, claiming a priority date of January 20, 1995).

The Examiner states that Salovey discloses "a method for crosslinking UHMWPE for forming in vivo implants. The method comprises irradiating crosslinking of a molten polymer." Applicants respectfully disagree with the examiner. Without acquiescing in the rejections, applicants herewith submit that the conception and reduction to practice of the inventions that relate to crosslinking polyethylene, including UHMWPE, by irradiation of the polymer in a molten state for improving the wear characteristics of polymeric material were achieved prior to January 20, 1995, which is the earliest listed filing date of U. S. patent No. 6,281,264. Applicants provide a copy of the rule 131 declaration (pursuant to 37 CFR § 1.131) filed in the related application (10/197,263). Therefore, Salovey *et al.* is not a prior art to instant application.

Moreover, as admitted by the examiner that Salovey differs by "the order of irradiation and melting." The examiner has not addressed the significance of this determination in view of the pending claims.

Salovey process differs substantially from the instant process as noted above. Therefore, withdrawal of the anticipation rejections is solicited.

On page 6 of the office action, the examiner rejected claims 126-129 and 147-149, and alleged as being anticipated by Shalaby *et al.* (5,824,411). The Examiner specifically states that Shalaby discloses "a method that comprises melting UHMWPE [...] and irradiating the resulting composite with high energy radiation to sterilize and crosslink composites of the UHMWPE." The Applicants point out that according to

Shalaby, "composites should be removed from the mold when mold temperature has dropped to below 70°C.," (see col 5 lines 65-67) and then "sterilized [ ] by radiation" (see col 6 lines 1-5). Thus, Shalaby does not teach heating of irradiated composites.

Therefore, the Examiner has failed to demonstrate that each and every claim term is contained in a single prior art reference. Applicants respectfully request the withdrawal of the rejections.

The examiner indicated that the declaration must be filed in the instant application in order to be considered in the instant application. Applicants herewith provide a copy of the Rule 1.131 declaration that was filed on July 16, 2004 in the related application (Serial No. 10/197,209) and show that the completion date of the instantly claimed invention is prior to January 20, 1995.

Accordingly, the Shen, Hyon, Salovey or Shalaby patents are not prior art. Therefore, applicants submit that the rejection should be withdrawn. See *In re Spiller*, 500 F.2d 1170 (CCPA 1974); *In re Stempel*, 241 F.2d 755 (CCPA 1957).

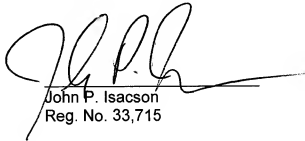
***Double Patenting Rejections:***

On pages 7-9 of the office action, the examiner has provisionally rejected claims under the judicially created doctrine of obviousness-type double patenting and alleged as being directed to the same invention as the claims of co-pending application serial nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089, and 10/197,263.

Because a notice of allowance for the 10/948,440, 10/197,209, 10/696,362, 10/901,089, or 10/197,263 applications has not been received, the merits of this provisional rejection need not be discussed with the examiner at this time. See MPEP § 822.01.

interference can be declared with applicants as the senior party by virtue of the priority afforded by the priority applications. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J.P. Isacson', with a long horizontal flourish extending to the right.

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Date

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